Development and validation of HPLC method for quantification of docetaxel in palm-based nanoemulsion aerosols

ABSTRACT

Lung cancer is the leading cause of cancer-related deaths worldwide. Among the most potent of chemotherapeutic drugs used for lung cancer treatment are the taxanes, including docetaxel. However, the drugs' efficacy in combating the disease is reduced due to their poor solubility, low stability and high toxicity. Inhalation therapy of lipid-based carrier has great potential in direct target towards the respiratory diseases. Hence, application of aerosolized palm-based nanoemulsion system is one approach to alleviate the drawbacks. This study describes the development and validation of method that can quantitate the amount of docetaxel nanoemulsion formulation via high-performance liquid chromatography (HPLC). Chromatographic analysis was conducted using a reversed phase C18 column with a mixture of acetonitrile and water (50:50) adjusted to pH 3.0 as the mobile phase. The flow rate was 1.0 mL/min and the detection was carried out by ultraviolet-visible detector at 228 nm. The developed method was validated in terms of specificity, linearity, accuracy and precision accordance with the International Conference on Harmonization (ICH) guidelines. The calibration curve was linear (r2= 0.999) over the concentration range from 62.5 to 1000 µg/mL with lower limit of detection (LOD) of 9.88 µg/mL and lower limit of quantification (LOQ) of 29.93 µg/mL. The percentage relative standard deviation for both intra and inter-day precision was less than 2%, while percentage recovery was more than 90%, indicating the precision and accuracy of the study. The developed HPLC method was proved as suitable and reliable for its intended application.

Keyword: Aerosols; Docetaxel; High-performance liquid chromatography; Nanoemulsion; Lung cancer